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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ebrahim Zandi

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7590

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EXAMINER

PROUTY, REBECCA E

ART UNIT

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1652

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/079,949	Applicant(s) ZANDI ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5-7,17-19,21-23 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5-7,17-19,21-23 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1, 3, 4, 8-16, 20 and 24-41 have been canceled. Claims 2, 5-7, 17-19, 21-23 and newly presented claim 42 are still at issue and are present for examination.

Applicants' arguments filed on 2/13/09, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 5-7, 17-19, 21-23, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 (upon which claims 5-7, 17-19, and 21-23 depend) is indefinite in the recitation of "said IKK gamma (γ) gene solely regulates activation of said IKK protein complex" as it is unclear what limitations this imposes on the claimed method. The IKK gamma protein inherently activates the IKK protein complex but what if any limitations the use of the phrase "solely" places on the yeast cell and/or the structure of the IKK proteins is not clear. Since it is wholly unclear what if any limitations the use of the word "solely" imparts, for further examination the word "solely" is not given any patentable weight.

Claims 5-7, 17-19, 21-23, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed fails to provide support for the recitation of "said IKK gamma (γ) gene solely regulates activation of said IKK protein complex" in Claim 42 (upon which claims 5-7, 17-19, and 21-23 depend). Applicants point to page 7, lines 6-14 and Examples 1 and 2 as providing support for claim 42. However, while these pages clearly describe that the IKK gamma protein inherently activates the IKK protein complex they in no way teach or describe the features of a yeast cell in which the IKK gamma protein is the sole means of activating the IKK protein complex.

The declaration filed on 2/13/09 under 37 CFR 1.131 is sufficient to overcome the Li et al. reference. Applicant should note that the declaration that was filed is still highly unclear what was done in each experiment and what each gel shows. However, applicants declaration states that similar gels and results are shown in Figure 3 and on page 15, lines 21-27 of

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the instant specification. The brief description of Figure 3 of the instant specification is clear as to what was done and it appears that the experiments of the declaration are essentially the same. In view of this the declaration has been deemed sufficient. However, if the conclusion that the experiments of the declaration are done by the procedures described by Figure 3 of the specification is incorrect applicants should so state on the record and the rejection will be reinstated unless applicants provide further explanation of what the experiments of the declaration show.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 5-7, 17-19, 21-23 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothwarf et al.

(Reference C27 of Applicant's PTO-1449) in view of Traincard et al. and Epinat et al. The rejection is explained in the previous Office Action.

Applicants argue that the art fails to teach or suggest the production of substantially homogenous and biologically functional IKK protein complex because Rothwarf et al. does not teach that the autophosphorylation of the IKK complex is regulated by the IKK γ subunit. Applicants submit that they were the first to disclose this. However, while Rothwarf et al. may not have explicitly disclosed that the IKK γ subunit regulates the autophosphorylation of the IKK complex this was clearly known in the art prior to applicants invention. (see for example column 25, lines 3-5 of US Patent 6,864,355 having priority to 5/22/00). Furthermore, as previously explained knowledge that the IKK γ subunit regulates the autophosphorylation of the IKK complex would not have been necessary for an expectation of production of substantially homogenous and biologically functional IKK protein in yeast as a skilled artisan would clearly expect all inherent functions of the α , β , and γ subunits to be present when they are coexpressed in any eukaryotic system. The fact that Rothwarf et al. suggest that another function of the IKK γ subunit may be to connect the IKK complex to upstream activators in no way teaches away from

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this expectation. Furthermore, Rothwarf et al. clearly teach the importance of phosphorylation of the IKK complex for its kinase activity and teach that the IKK complex can be phosphorylated *in vitro* by the NIK and MEKK1 proteins to produce an active complex. Applicants again repeat the reference to a declaration by Dr. Zandi which states that "Rothwarf et al., supra, on page 297, right column, lines 16 - 19, teaches that IKK- α/β can be phosphorylated and activated by overexpression of NIK and MEKK1 in mammalian cells, but does not teach that the IKK complex from yeast of the present application containing IKK α , IKK β , and IKK γ can be activated by NIK or MEKK1 in yeast systems. Rothwarf et al. also teaches that the physiological role of NIK and MEKK1 in IKK activation by pro-inflammatory cytokines is not clear." However, this statement is insufficient to overcome the explicit teaching by Rothwarf et al. that overexpression of NIK and MEKK1 can be used for activation of the IKK complex. It is not necessary for a skilled artisan to have an expectation that these are the physiological activators, merely that the overexpression of them provides the necessary activation of the complex. The declaration provides no reason for believing that overexpressing NIK or MEKK1 wouldn't have the same effect on the IKK complex in

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yeast cells that it has in mammalian cells. As such the rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be

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reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
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